

**IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION**

**IN RE: AREDIA® AND ZOMETA®
PRODUCTS LIABILITY LITIGATION
(MDL No. 1760)**

**This Document Relates to:
ALL CASES**

No. 3:06-MD-1760

**JUDGE CAMPBELL
MAGISTRATE JUDGE BROWN**

PROTECTIVE AND CONFIDENTIALITY ORDER

It is hereby **ORDERED** and **ADJUDGED**, that:

- (1) This Protective and Confidentiality Order ("Protective Order") governing the disclosure of confidential, proprietary and other protected information by any party is hereby entered in all actions in *In re: Aredia® and Zometa® Products Liability Litigation*, No. 3:06-MD-1760 (M.D. Tenn.) ("MDL 1760"). This Order shall apply to all cases currently a part of MDL 1760, as well as all cases subsequently filed in, removed to, or transferred to this Court as part of MDL 1760. In cases subsequently filed in this district, the Clerk shall provide a copy of this Order to each plaintiff at the time of filing of the complaint. In cases subsequently removed or transferred to this Court, the Clerk shall provide a copy of this Order to each new party upon removal or transfer. This Order vacates any prior protective or confidentiality order issued by a federal court prior to the transfer of a case to MDL 1760, including any orders entered in matters pending before this Court prior to entry of the Order of the Judicial Panel on Multidistrict Litigation creating this MDL. However, any material that was previously

designated as Confidential pursuant to any prior order and that would also qualify for such a designation pursuant to this Protective Order is automatically deemed protected by this Protective Order.¹

- (2) For purposes of this Protective Order, any Party may designate as "Confidential Material" any information regarded as confidential by the Party that is contained in any document, written discovery response, testimony, or other material produced or provided by that Party or its representative(s) to any other Party, whether provided voluntarily, pursuant to formal discovery procedures, or otherwise.
- (3) Any Party may designate a document as Confidential Material by stamping it "Confidential," or "Subject to Protective Order." All pages of any document that bears such a legend are subject to this Protective Order. The Party shall affix the stamp in such a manner so as not to obscure the text of the document.
- (4) To the extent that matter stored or recorded in the form of electronic or magnetic media (including information, files, databases or programs stored on any digital or analog machine-readable device, computers, Internet sites, discs, networks or tapes) ("Computerized Material") is produced by any party in such form, the producing Party may designate such materials as Confidential by marking the container that the media is produced in "Confidential." Whenever any party to whom Computerized Material designated as Confidential is produced reduces

¹ Collectively, Defendant Novartis Pharmaceuticals Corporation ("NPC") and plaintiffs whose cases are currently a part of MDL 1760, or whose cases are subsequently filed in, removed to, or transferred to this Court as part of MDL 1760 will be referred to herein as the "Parties."

such material to hardcopy form, that party shall mark the hardcopy form with the "Confidential" designation.

- (5) If responses to interrogatories, requests for admission, or other written responses to discovery quote, summarize, or contain Confidential Material, the Parties may designate them as Confidential Material by marking the face of any such response with one of the legends set forth in paragraph (3) above and indicating the page and line references of the material that is to be subject to this Protective Order.
- (6) A Party may designate the transcript of any deposition in this Action or any portion thereof, including exhibits thereto, as Confidential Material by either so advising the court reporter and the Parties on the record during the taking of the deposition or within thirty (30) days after receipt of the deposition transcript by written designation served upon the Parties. If all or any portion of a deposition is designated as being subject to this Protective Order, the court reporter and any Parties possessing any transcripts shall label the cover page of each transcript or copy thereof to state that the deposition includes Confidential Material, and shall label as confidential each of the pages of the transcript or exhibits that contain Confidential Material.
- (7) Any inadvertent production of any confidential or proprietary material will not result in or be construed as a waiver, in whole or in part, of (a) the producing Party's claims of confidentiality either as to the specific information inadvertently disclosed or more generally as to the subject matter of the information disclosed, or (b) the party's right to designate the material as confidential pursuant to this Protective Order. In the event that a Party inadvertently produces any

Confidential Material without attaching one of the legends described in paragraph (3) above, the Party may subsequently designate the material as Confidential at any time by forwarding to the opposing Party copies of the material bearing one of the legends required by paragraph (3) and requesting that the opposing Party destroy all prior copies of the Confidential Material. Upon receipt of such a request, the opposing Party shall destroy all copies of the Confidential Material produced inadvertently and replace them with copies bearing the appropriate confidentiality legend.

- (8) Written and oral communications between or among counsel for the Parties that refer to or discuss Confidential Material automatically shall be subject to this Protective Order.
- (9) Confidential Material shall be treated by the Parties and their counsel as being confidential and private. Any copy made of Confidential Material shall have the same status as the original. The disclosure and use of Confidential Material shall be confined to the permissible disclosures and uses set forth below. NPC's Confidential Material shall be used (if otherwise relevant and admissible) solely for the litigation of actions under or subject to MDL 1760, including any appeals, and for any other Aredia[®] and/or Zometa[®] action pending in a state court where the state court has entered a protective order offering substantially equivalent or greater protection for NPC's Confidential Material ("Permitted State Court Actions"). A determination that a state court protective order provides substantially equivalent or greater protection must be expressly made and agreed to by the parties to that protective order or by the presiding court. Confidential

Material shall not be used in any other legal action or proceeding or for any other purpose without further order of this Court. All other disclosure and use of Confidential Material during the pendency of this Action or after its termination is hereby prohibited.

(10) Confidential Material may be disclosed only to the following persons and only insofar as it is reasonably necessary to the effective prosecution of the Parties' claims and defenses:

- (a) Parties, their representatives, in-house counsel and regular employees who are actively engaged in, or actively overseeing an action docketed in or pending in MDL 1760, a Permitted State Court Action, or involved in complying with NPC's legal obligations to provide information to the Food and Drug Administration;
- (b) Counsel of record for action(s) docketed in or pending in MDL 1760, or action(s) subsequently filed in, removed to, or transferred to this Court as part of MDL 1760 or a Permitted State Court Action, including their associated attorneys, paralegal and secretarial personnel, and other support staff;
- (c) Counsel of record for other filed actions involving Aredia® and/or Zometa®, including their associated attorneys, paralegal and secretarial personnel, and other support staff, provided that a protective order providing substantially equivalent or greater protection for NPC's Confidential Information has been entered by the court in the other filed action;
- (d) Experts and consultants (including their employees) who are retained by a Party to assist in the litigation of actions docketed or pending in MDL 1760 or a Permitted State Court Action;
- (e) Third-party contractors and their employees who are retained by one or more Parties to provide litigation-support or copy services in connection with the litigation of actions docketed or pending in MDL 1760 or a Permitted State Court Action;
- (f) Witnesses or prospective witnesses in actions docketed or pending in MDL 1760 or a Permitted State Court Action;

- (g) Court reporters and other persons involved in recording deposition testimony in actions docketed or pending in MDL 1760 or a Permitted State Court Action;
- (h) Court personnel of the United States District Court for the Middle District of Tennessee, other courts involved in actions docketed or pending in MDL 1760, a Permitted State Court Action, or, if on appeal, of a court with appellate jurisdiction;
- (i) Jurors in actions docketed or pending in MDL 1760 or a Permitted State Court Action; and
- (j) The Food and Drug Administration, to the extent NPC is required to disclose any Confidential Material by law.

Counsel for each Party disclosing Confidential Material in accordance with this paragraph shall (i) advise each person to whom such disclosure is made (except Court personnel, jurors, and the Food and Drug Administration) of the terms of this Protective Order and of the obligation of each such person to comply with those terms and (ii) provide a copy of this Protective Order to each such person. Prior to the disclosure of any Confidential Information to any person identified in subparagraphs c, d, e, f, and g above, such person shall sign an Acknowledgment, in the form attached hereto as Exhibit A, acknowledging that he or she has read this Protective Order and shall abide by its terms. Counsel shall maintain a list of persons to whom confidential materials are disclosed (excluding jurors, Court personnel, and the Food and Drug Administration). Upon learning of any disclosure of Confidential Material to any person not authorized by this paragraph to receive Confidential Material, the Party who so learns shall immediately (i) inform in writing the Party from which the Confidential Material was originally received of such disclosure, including to whom the material was disclosed, and (ii) take all necessary steps to retrieve as soon as possible each and

every copy of all Confidential Material from the unauthorized person and any person to whom the unauthorized person disclosed the Confidential Material.

- (11) Disclosure of Confidential Material in accordance with this Protective Order shall not effect, nor shall it be deemed to effect, a waiver of the attorney-client privilege, the work-product immunity, or any other privilege or immunity from disclosure to which such Confidential Material may be entitled, whether in actions subject to MDL 1760 or in any other action or as to any non-party.
- (12) Documents bearing confidentiality designations shall not be used as exhibits at trial. Before trial, and upon request, the producing Party shall provide copies of such documents free of any confidentiality designation for use at trial. Such documents shall be used only for trial purposes and shall be returned, along with any and all copies made, to the producing Party after this case is finally determined as to the Party to whom the documents were produced.
- (13) Each Party agrees that in the event it is served by a non-party with a subpoena or request for production of Confidential Material originally received from another Party, it will give sufficient notice to allow that Party a reasonable opportunity to intervene to oppose such production. The notice shall include a description of the material sought, the date and location for compliance with the subpoena or request, the identity of the requester of the Confidential Material, the docket number of the matter where requested and all other information reasonably necessary to intervene and oppose such production.
- (14) Should any Party to whom Confidential Material is disclosed object to the designation of that material as proprietary, confidential, or otherwise protected, it

shall make a good-faith effort to resolve the dispute informally with the disclosing Party. Except where good cause is shown, all objections to the designation of documents as Confidential Material must be interposed in writing no later than thirty (30) days prior to the close of merits discovery, or such objections shall be deemed waived. Should the Parties be unable to resolve the dispute, the Party opposing the inclusion of such material under this Protective Order, within a reasonable time, may apply in writing to the Court for a ruling that the information should not be entitled to protection under this Protective Order. The Party designating the material as confidential shall have the burden of proving that said material is subject to protection. Until such time as the Court rules on the motion, the material that is the subject of the dispute shall continue to be subject to this Protective Order.

- (15) The inadvertent production by any Party in the course of discovery in these proceedings of a document subject to a claim of privilege, work product, or other statutory or court-ordered confidentiality, will not result in a waiver of any of the foregoing protections, whether in these or any other proceedings, for the produced document or any other withheld document covering the same or similar subject matter. If any Party should inadvertently produce a document, upon notice of such disclosure, all originals and copies thereof, shall be immediately returned to the producing Party, and such returned material shall be deleted from any litigation-support or other database. All notes or other work product reflecting the contents of such inadvertently disclosed Confidential Materials shall be destroyed and receiving counsel shall certify in writing to the producing party's counsel that

any notes or other work product reflecting the inadvertently disclosed document's contents have been destroyed by counsel, the receiving party, and any experts or others in their employment.

- (16) When a Party wishes to use a document that has been designated as confidential in support of a motion or other filing with the Court, it will consult with the Party that has made the confidentiality designation (a) to resolve a way to present the evidence without the necessity of filing it with the Court; or (b) if no such resolution can be reached, to arrange for appropriate protection under seal.
- (17) This Protective Order shall not prevent the Parties from using or disclosing their own documents and other materials in any manner, notwithstanding their designation as Confidential Material subject to this Protective Order. The use or disclosure by a Party of its own documents or materials shall not terminate, waive or otherwise diminish in any way the status of such documents or materials as Confidential Materials subject to this Protective Order.
- (18) Upon the final determination, including any appeals related thereto, of all cases made part of MDL 1760 (or such other case in which an attorney is permitted by this Protective Order to use Confidential Material), NPC will send a letter to Plaintiffs' Liaison Counsel advising him that the litigation is concluded and that all Confidential Material should be returned or destroyed. Within thirty (30) days after receipt of that letter, all attorneys in possession of Confidential Material shall return all Confidential Material to the disclosing Party or, alternatively, shall immediately destroy all such material. All counsel of record shall, within forty-five days of this final determination, certify that all Confidential Material,

including any such material disclosed to any other entity, has been returned or destroyed. The sole exception to the requirements described above is that information that has been incorporated into attorney work product or other privileged documents need not be returned or destroyed. Such information shall be retained by the person to whom the information was produced, and shall be treated as Confidential Material in accordance with this Order.

- (19) This Protective Order shall not enlarge or affect the proper scope of discovery in this or any other litigation, nor shall this Protective Order imply that material designated as Confidential Material under the terms of this Protective Order is properly discoverable, relevant or admissible in this or any other litigation.
- (20) Each Party shall retain all rights and remedies available to it under the law for the enforcement of this order against anyone who violates it.
- (21) The restrictions of this Protective Order shall continue to apply after actions subject to MDL 1760 are finally determined and the Court shall retain jurisdiction for all purposes in connection therewith. All persons receiving or given access to Confidential Material in accordance with the terms of this Protective Order consent to the continuing jurisdiction of the Court for the purposes of enforcing this Protective Order and remedying any violations thereof.

IT IS SO ORDERED.

SIGNED AND ENTERED this 16th day of August, 2006

/s/ Joe B. Brown
JOE B. BROWN
UNITED STATES MAGISTRATE JUDGE